

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Anthony P. Shuber  
Title: Methods for Disease Detection  
Patent No.: 6,919,174  
Issued: July 19, 2005  
Serial No. 09/514,865  
Filing Date: February 28, 2000

USPTO  
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United States Patent and Trademark Office  
P.O. Box 979070  
St. Louis, MO 63197-9000

**Notification Of Loss Of Entitlement To Small Entity Status**  
**Under 37 CFR 1.27(g)(2)**

Sir:

This paper is being filed pursuant to 37 CFR 1.27(g)(2).

37 CFR 1.27(g)(2) states:

*(g) (2) Notification of loss of entitlement to small entity status is required when issue and maintenance fees are due. Notification of a loss of entitlement to small entity status must be filed in the application or patent prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity as defined in paragraph (a) of this section is no longer appropriate. The notification that small entity status is no longer appropriate must be signed by a party identified in § 1.33(b). Payment of a fee in other than the small entity amount is not sufficient notification that small entity status is no longer appropriate.*

37 CFR 1.28(c) states:

*c) How errors in small entity status are excused If status as a small entity is established in good faith, and fees as a small entity are paid in good faith, in any application or patent, and it is later discovered that such status as a small entity was established in error, or that through error the Office was not notified of a loss of entitlement to small entity status as required by § 1.27(g)(2), the error will be excused upon: compliance with the separate submission and itemization requirements of paragraphs (c)(1) and*

(c)(2) of this section, and the deficiency payment requirement of paragraph (c)(2) of this section:

(1) *Separate submission required for each application or patent. Any paper submitted under this paragraph must be limited to the deficiency payment (all fees paid in error), required by paragraph (c)(2) of this section, for one application or one patent. Where more than one application or patent is involved, separate submissions of deficiency payments (e.g., checks) and itemizations are required for each application or patent. See § 1.4(b).*

(2) *Payment of deficiency owed. The deficiency owed, resulting from the previous erroneous payment of small entity fees, must be paid*

(i) *Calculation of the deficiency owed. The deficiency owed for each previous fee erroneously paid as a small entity is the difference between the current fee amount (for other than a small entity) on the date the deficiency is paid in full and the amount of the previous erroneous (small entity) fee payment. The total deficiency payment owed is the sum of the individual deficiency owed amounts for each fee amount previously erroneously paid as a small entity. Where a fee paid in error as a small entity was subject to a fee decrease between the time the fee was paid in error and the time the deficiency is paid in full, the deficiency owed is equal to the amount (previously) paid in error;*

(ii) *Itemization of the deficiency payment. An itemization of the total deficiency payment is required. The itemization must include the following information:*

(A) *Each particular type of fee that was erroneously paid as a small entity, (e.g., basic statutory filing fee, two-month extension of time fee) along with the current fee amount for a non-small entity;*

(B) *The small entity fee actually paid, and when. This will permit the Office to differentiate, for example, between two one-month extension of time fees erroneously paid as a small entity but on different dates;*

(C) *The deficiency owed amount (for each fee erroneously paid); and*

(D) *The total deficiency payment owed, which is the sum or total of the individual deficiency owed amounts set forth in paragraph (c)(2)(ii)(C) of this section.*

(3) *Failure to comply with requirements. If the requirements of paragraphs (c)(1) and (c)(2) of this section are not complied with, such failure will either: be treated as an authorization for the Office to process the deficiency payment and charge the processing fee set forth in § 1.17(i), or result in a requirement for compliance within a one-month non-extendable time period under § 1.136(a) to avoid the return of the fee deficiency paper, at the option of the Office.*

In accordance with the above-identified rules, Applicant presents the following relevant facts.

Facts:

After the filing of the above-referenced patent application on February 28, 2000, the inventor assigned all of his rights in the application to Exact Laboratories, Inc. ("EXACT"). The assignment was subsequently recorded with the United States Patent and Trademark Office ("USPTO") at Reel No. 010964 and Frame No. 00872. EXACT was a small entity; entitlement to small entity status was asserted, and the application was accorded small entity status by the USPTO.

After the filing of the application, EXACT changed its name to Exact Sciences Corporation ("EXACT") on May 9, 2000. The change of name was recorded with the USPTO at Reel No. 011676 and Frame No. 0640. EXACT was a small entity; entitlement to small entity status was asserted, and the application was accorded small entity status by the USPTO.

After the issuance of the patent, EXACT was acquired by Genzyme Corporation ("GENZYME"). The assignment from EXACT to GENZYME was subsequently recorded with the USPTO at Reel No. 022460 and Frame No. 0934. GENZYME was a small entity; entitlement to small entity status was asserted, and the patent was accorded small entity status by the USPTO.

This patent was acquired from GENZYME by Laboratory Corporation of America Holdings ("LABCORP"), which is a large entity. The assignment from GENZYME to Esoterix Genetic Laboratories, LLC, which is a subsidiary of LABCORP, was subsequently recorded with the USPTO at Reel No. 025656 and Frame No. 0581. In accordance with 37 C.F.R. § 1.27(g)(2), notification of loss of small entity status must be given to the USPTO when paying the maintenance fee due after the date on which status as a small entity is no longer appropriate. The small entity status does not appear to have been made at the time of payment. Applicant is hereby notifying the USPTO of the loss of entitlement to small entity status for the patent. Accordingly, the twelfth year maintenance fee should be paid as a large entity.

Applicant believes that an additional fee is necessary in the amount of \$2405 as the deficiency of the twelfth year maintenance fee for a large entity. Further, in accordance with 37

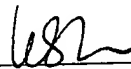
CFR 1.28(c), Applicants respectfully request that the erroneous payment of small entity fees be excused.

The Commissioner is hereby authorized to charge any fees required by this action or any future action to Deposit Account No. 20-1430.

Should there be any questions relating to the instant application, the Patent Office is invited to telephone the undersigned at (336) 607-7442 to discuss any issues.

Respectfully submitted,

Date: 3 January 2013

  
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